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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,214	03/22/2001	David C. Paul	8932-342	2300

20582 7590 10/23/2002

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,214

Applicant(s)

PAUL ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The Amendment filed 8/13/02 has been entered as Paper No. 8. Changes to the abstract have been approved by the Examiner. Claims 1, 2, 13, 14 and 16 have been amended and new claims 17-34 have been added.

Information Disclosure Statement

2. The Information Disclosure Statement filed 8/13/02 has been entered as Paper No. 9. A copy of each of the non-patent references listed under "Other References" was not currently available to the Examiner for consideration. The U.S. and foreign patent documents have been considered, as indicated in the initialed and signed PTO-1449. Examiner is requesting applicant to resend a copy of each of the 6 other references with the response to this office action in order for them to be considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 7 is indefinite because it is unclear how the at least two bone fragments can be coupled together to form a substantially enclosed hollow region therebetween, as required by

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amended claim 1, and be concentric hollow cylinders, as required by claim 7. Figures 4A-5E show coupled bone fragments forming a hollow region, but do not show the fragments being concentric hollow cylinders.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-3, 7-13, 16-19, 23, 24 and 27-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Grooms et al. (US Patent Application Number 2002/0138143, which is related to WO 99/09914 as cited in applicant's IDS).

Grooms et al. discloses a cortical bone cervical fusion implant with all the elements of claims 1, 16 and 27. See Figure 8A and paragraphs [0010], [0018], [0024] and [0049] for bone fusion implant (800) comprising a hollow body with a completely enclosed hollow region (when fragments are connected) formed between at least two bone fragments (801A, 801B) which are configured and dimensioned for mutual engagement and which are coupled together. The outer surface has a contour conforming in shape with the end plate of vertebrae. See Figure 1C and paragraph [0034] for additional limitation of implant shown in Figure 8A having migration resistant feature.

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Claims 2, 17, and 29, see paragraphs [0048] and [0049].

Claim 3, see paragraph [0049] for pin-hole providing as male-female mating relationship.

Claim 7 is indefinite as explained supra. It is not accurate that the two bone fragments are concentric hollow cylinders as shown in Figures 4A-5E.

Claims 8, 18, and 30, see abstract and paragraph [0057] for core formed of bone material and disposed in the hollow body.

Claims 9, 19, and 31, see paragraph [0057] for cancellous bone with a fluid (glycerol) concentrated therein.

Claims 10-12 are product-by-process claims, and according to MPEP § 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. The implant of Grooms et al. includes cancellous bone with fluid concentrated therein, thereby meeting the structural limitations of claims 10-12.

Claim 13, see paragraph [0010] for bone comprising autograft or allograft bone tissue.

Claims 23, 24, and 27, see Figure 8A and for outer surface contour.

Claim 27, see rejection to claim 1, supra. See Figure 1C and paragraph [0034] for additional limitation of implant shown in Figure 8A having migration resistant feature.

Claim 28, see paragraph [0034] for teeth.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4-6, 14, 15, 20, 21, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. in view of Boyce et al. (USPN 6,123,731).

Grooms et al. discloses a cortical bone cervical fusion implant with all the elements of claim 1, but is silent to the specific coupling connections of required by claims 4-6. Examiner contends that these required couplings are well known in the art to be equivalents, as taught by Boyce et al. Boyce et al. teaches an osteoimplant using the required forms of couplings in order to hold the bone fragments together. See column 5, lines 61-67. Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to teachings of Boyce et al. to use any of the couplings to hold the bone fragments together.

Grooms et al. is also silent to the bone tissue of the bone fragments being partially demineralized or demineralized and at least partially dehydrated, as required by claims 14, 20, 32 and claims 15, 21, 33, respectively. Boyce et al. teaches demineralizing the bone fragments in order to increase the compression strength of the bone (column 4, lines 6-9) and dehydrating the bone fragments in order achieve cross-linking of the bone fragments (column 7, lines 40-43). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Boyce et al. to demineralize and dehydrate the bone fragments of Grooms et al. in order to increase the compression strength and cross-link the bone fragments.

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9. Claims 22, 26 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. in view of Coates et al. (USPN 5,989,289 as cited in previous office action PTO-892).

Grooms et al. discloses a cortical bone cervical fusion implant with all the elements of claims 1, 16 and 27, but is silent to the implant comprising a region sized to receive a surgical instrument, as required by claims 22, 26 and 34. Coates et al. teaches a bone graft with a tool engaging hole in order to receive a tool used for implantation. See Figures 8 and 9 and column 9, lines 60-64. It would have been obvious to one of ordinary skill in the art to modify the implant of Grooms et al. to include a region sized to receive a surgical instrument, as taught by Coates et al., in order for a surgeon to be able to use a tool in implanting the fusion implant.

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. in view of Scarborough et al. (USPN 5,895,426 as cited in previous office action PTO-892).

Grooms et al. discloses a cortical bone cervical fusion implant with all the elements of claim 1, but is silent to the implant comprising an outer surface with a wedge-shaped profile, as required by claim 25. Scarborough et al. teaches a fusion implant device having a wedge-shaped profile in Figure 28 and column 8, lines 32-38. Examiner contends that a wedge-shaped intervertebral implant is known in the art to provide the spine with the natural curvature.

Therefore, it would have been obvious to one of ordinary skill to look to the teachings of Scarborough et al. to make the implant of Grooms et al. have a wedge-profile in order to provide the spine with a natural curve.

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Response to Arguments

11. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

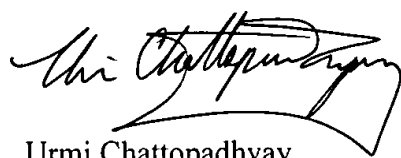
12. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 8/13/02 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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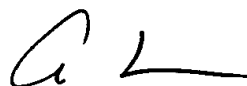
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



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October 18, 2002